PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 17 April 2001 (17.04.01)	
International application No. PCT/IE00/00093	**Applicant's or agent's file reference** P8145.WO
International filing date (day/month/year) 28 July 2000 (28.07.00)	**Priority date** (day/month/year) 30 July 1999 (30.07.99)
Applicant CALDWELL, Martin et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

23 February 2001 (23.02.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION ATY

PCT PTO/PCT Rec'd 29 JAN 2002

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P8145.WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IE00/00093	28/07/2000	30/07/1999
International Patent Classification (IPC) or national classification and IPC A61B17/00		
Applicant GAYA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23/02/2001	29.11.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fontenay, P Telephone No. +49 89 2399 2646

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00093

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1,4-10,12-15,17, 18	as originally filed	
1a,2,3,11,16	with telefax of	05/11/2001

Claims, No.:

1-25	with telefax of	05/11/2001

Drawings, sheets:

1/12-12/12	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☒ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Yes: Claims 1-25

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-25
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations
see separate sheet

Reference is made to the following documents:

D1: EP-A-542428
D2: US-A-5658306

Re Item V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 The subject-matter of claim 1 is new and inventive in the sense of Article 33(2) and 33(3) PCT.

Document D2, which is considered to illustrate the closest prior art as to the subject-matter of claim 1 discloses a surgical instrument for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body (see D2, column 1, lines 34-38; column 11, lines 43-54). The surgical device disclosed in D2 is also formed to allow insertion of medical equipment and comprises a cannula (guide member 162) defining a conduit in the patient and a trocar (outer guide member 167) carried on the cannula (162) and formed for piercing or cutting tissue to position the cannula (162) (see D2, column 10, line 36 - column 11, line 54 and figures 17, 18). Fixing means (172, 173, 174) for securing the cannula in position (see D2, column 10, lines 49-57) are also provided in D2. It is also noted that the trocar disclosed in D2 is removably mounted on the cannula (see column 10, lines 46-48) and can be inserted into the body cavity through the access port and to cut or pierce tissue outwardly from within the body cavity out to an operating site (see D2, column 11, lines 43-54).

The subject-matter of claim 1 differs from this known surgical device in that the trocar provides a gas-tight cap for the cannula when the trocar is mounted on the cannula.

There is no hint in D2 in order to modify the trocar (outer guide member 167) in D2 so as to provide a gas tight cap. In the contrary, in D2, the cannula should be able to protrude out of the distal end of the trocar (see D2, column 11, lines 43-56)

which would not be possible with a cap configuration.

The claimed subject-matter differs from the device disclosed in D1 in that the trocar is on the cannula. The claimed subject-matter is accordingly also new and inventive over Document D1.

V.2 The claims 2-25 refer to preferred embodiments of the circulatory support system according to claim 1. The subject-matter of claim 1 being considered as new and inventive, the same applies to said preferred embodiments. The subject-matter of claims 1-25 is accordingly also new and inventive

It is an object of this invention to provide a method and apparatus for inserting and using a cannula, which will overcome the aforementioned problems.

It is a further object of the invention to provide a method and apparatus for securing and using a cannula, which will overcome the aforementioned problems and which will reduce the risk of secondary seeding of cancerous cells at port sites.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

wherein the trocar is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site. In this way accidental damage to the patient's tissue or organs is prevented as the cutting or piercing point of the trocar is directed away from the patient's body during the fixing procedure.

Ideally, the device is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site. Thus, the action of the cannula piercing the body cavity wall automatically draws the cannula into position.

Preferably, the trocar is removably mounted on the cannula.

In a particularly preferred embodiment, the trocar and cannula are connected with complementary engageable short threads on the trocar and cannula, such as quarter turn threads.

In one arrangement, the trocar is formed to provide a gas-tight cap for the cannula when mounted thereon. In this way as the trocar pierces outwardly from the body cavity there is no escape of gas, which would collapse the cavity. This is particularly useful when a single external valve is used.

In one arrangement, the trocar is provided with an integral cutting element. This facilitates the cutting of the body cavity wall to allow introduction of the cannula.

Preferably, the trocar incorporates an extension shoulder, thereby allowing the trocar to define a narrow incision, which is gently extended to ensure that the drawn cannula is firmly lodged in the body cavity wall preventing loss of gas from the cavity.

Preferably, the trocar incorporates guard means for protecting a surgeon's hand from being cut when being introduced into the body cavity or as the device cuts the patients skin thereby preventing injury to the surgeon.

Preferably, the cannula incorporates means for attaching the cannula to an interior of the body cavity when in position.

Ideally, the means for attaching the cannula to an interior of the body cavity is provided by an internal distal ring.

In one arrangement, the internal distal ring and the cannula are integrally formed as a single unit.

It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.

It will also be understood that the method and apparatus described may with minor modifications and without departing from the scope of the invention, be used to insert the device from an exterior surface through the abdominal wall into a patient's interior.

To avoid unnecessarily obscuring the present invention, detailed description of the valve has not been included, as it will be apparent to those skilled in the art that a wide variety of valves may be successfully employed. One such possibility is a twist valve, but any suitable valve may be used.

Referring now to Figs. 7 and 8 there is illustrated one example of a valve for use with the device indicated generally by the reference numeral 700 in which parts illustrated in Figs. 1 to 6 are indicated by the same numerals generally. With the device in position the valve 700 is located within the body cavity. A pair of doors 701 hingedly connected to the cannula 6 provides the valve. The doors 701 are biased into a closed position by a rubber cover 702. When a surgical implement 703 is inserted into the cannula (See Fig. 8) the doors 701 are forced outwardly against the cover 702. The cover 702 seals around the surgical implement 703 preventing escape of air from the cavity and as the implement is removed they also act to close the doors 701.

Referring now to Figs. 9 and 10 there is illustrated a further embodiment of a surgical device indicated generally by the reference numeral 900 in which parts similar to those described with reference to Figs. 1 to 8 are identified by the same numerals generally.

In this embodiment, the device 900 incorporates a releaseably attachable external seal housing 901 and an internal one way valve 902 mounted about opposing ends of the cannula 6. The housing 901 is located on the cannula 6 when in position on the patient using O rings 905. The housing 901 incorporates a diaphragm seal 903 and defines an outwardly directed extended entry port indicated at 904. The entry port 904 has a conical

Referring now to Figs. 21 and 22, there is illustrated one such seal forming part of the invention indicated generally by the reference numeral 9000. The seal 9000 has a locking ring 9010, a diaphragm seal 9020 and two slit seals 9030, 9040. The slit seals 9030, 9040 each have four orthogonally arranged slits 9050 radiating from the center and the seals 9030, 9040 are offset by forty five degrees. In use, a seal is provided as an instrument is introduced by the action of pressing the instrument against the slits 9050. When the device is removed, the slits 9050 return to normal resting position offset by forty five degrees from the slit above thereby maintaining an overall seal.

Figs. 23 and 24 show a similar seal to that illustrated in Figs. 21 and 22 illustrated generally by the reference numeral 9500. In this seal 9500 the slits 9050 are orthogonally directed as before on a concave disc 9510. The concave nature of the disc 9510 ensures that the slits 9050 are pressed together. Upward movement beyond a resting position of any portion of the disc 9510 is prevented by the provision of four webs 9511 on the underside of the disc 9510 intermediate the slits 9050.

It will be noted that the invention is directed to wards providing a reduced trauma, low profile, airtight cannula. It will be appreciated also that the device is particularly suited for use with a trocar and is ideal for applications in which the device is positioned from within the body cavity. Thus, the invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is directed away from the patient's body during insertion.

It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.

It will also be understood that the method and apparatus described may with minor modifications and without departing from the scope of the invention, be used to insert the device from an exterior surface through the abdominal wall into a patient's interior.

CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula (6) defining a conduit into the body cavity;

a trocar (5) carried on the cannula (6) and formed for piercing or cutting tissue to position the cannula (6); and

fixing means for removably securing the cannula (6) in position on the patient during surgery,

characterised in that the trocar (5) is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site.

2. A surgical device as claimed in claim 1, wherein the trocar (5) is removably mounted on the cannula (6).

3. A surgical device as claimed in claim 2, wherein the trocar and cannula are removably mounted with complementary engageable short threads.

4. A surgical device as claimed in claim 2 or 3, in which the trocar is formed for gas-tight mounting on the cannula.

5. A surgical device as claimed in any preceding claim, wherein the trocar is provided with an integral cutting element, thereby facilitating the cutting of the body cavity wall to allow introduction of the cannula.

6. A surgical device as claimed in claim 5, wherein the trocar incorporates an extension shoulder.

7. A surgical device as claimed in any preceding claim, wherein the trocar incorporates guard means for preventing injury to the surgeon.

8. A surgical device as claimed in any preceding claim, wherein the cannula incorporates means for releaseably attaching the cannula to an interior of the body cavity.

9. A surgical device as claimed in claim 8, wherein the means for attaching the cannula to an interior of the body cavity is provided by an internal distal ring.

10. A surgical device as claimed in claim 10, in which the internal distal ring and the cannula are integrally formed as a single unit.

11. A surgical device as claimed in any preceding claim, wherein the cannula incorporates a valve to prevent loss of gas from the body cavity when the cannula is in position.

12. A surgical device as claimed in any preceding claim, wherein the fixing means incorporates an anchor ring formed for releasable engagement with a proximal end of the cannula extending from the body when the cannula is in position in the body cavity.

13. A surgical device as claimed in claim 12, wherein the anchor ring incorporates a thread for engaging on the same thread used to secure the trocar prior to installation of the cannula.

14. A surgical device as claimed in claim 12 or 13, wherein the anchor ring incorporates a valve.

15. A surgical device as claimed in any preceding claim, incorporating an external seal and an internal valve, the seal and valve being mounted about opposing ends of the cannula.

16. A surgical device as claimed in claim 15, wherein the cannula is integrally formed with the seal and valve.

17. A surgical device as claimed in claim 15 or 16, wherein the valve is integrally formed at one end of the cannula and has means for releaseably engaging a seal housing at an opposing end.

18. A surgical device as claimed in claim 17, in which the seal housing incorporates a diaphragm seal.

19. A surgical device as claimed in any of claims 15 to 18, wherein the seal housing defines an extended entry port.

20. A surgical device as claimed in claim 19, wherein the entry port has a conical section.

21. A surgical device as claimed in any preceding claim, wherein the cannula incorporates an insufflation port.

22. A surgical device as claimed in claim 21, in which the insufflation port communicates with an insufflation lumen having insufflation ducts communicating between the port and the body cavity.

23. A surgical device as claimed in claim 22,wherein the insufflation lumen is carried on an exterior surface of the cannula.

24. A surgical device as claimed in any of claims 13 to 23, wherein the anchor ring incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

25. A surgical device as claimed in any of claims 13 to 24, wherein the distal ring incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

26. A surgical device as claimed in any preceding claim, incorporating a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to being fixed in position on a patient.

27. A surgical device as claimed in any preceding claim, incorporating an adjustable pressure release valve.

28. A method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the trocar out to an operating site and inserting a cannula in the incision made using the trocar.

29. A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing

means for removably securing the cannula in position on the patient during surgery, the fixing means in turn having at least one seal, the or each seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

30. A surgical device as claimed in claim 29, in which the fixing means is provided by:- an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

an external seal having an downwardly extending conduit carried on an external mounting ring, the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

31. A surgical device as claimed in claim 30, wherein the conduits are formed for slidable interengagement.

32. A surgical device as claimed in claim 29 or 30, in which the conduits incorporate a ratchet retainer.

33. A surgical device as claimed in claim 32, wherein the or each conduit is deformable to facilitate removal by disengaging the ratchet retainer.

34. A surgical device as claimed in any of claims 30 to 33, wherein the, or each mounting ring has an associated pressure absorption and seal enhancement means.

35. A surgical device as claimed in any of claims 30 to 34, wherein the cannula incorporates a valve.

36. A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery

provided by an external and an internal mounting ring, one or both rings being pivotally movable about a longitudinal axis of the cannula.

37. A surgical device as claimed in claim 36, in which the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.

38. A surgical device as claimed in claim 37, in which the cannula is provided by a section of pleated tubing carried on the device.

39. A surgical device as claimed in claim 38, wherein the external mounting ring defines an entry funnel having an oversize entry aperture for receiving and facilitating insertion of a piece of medical equipment.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Int llectual Property Organization
International Bureau

(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/08563 A2

(51) International Patent Classification[7]: A61B 17/00

(21) International Application Number: PCT/IE00/00093

(22) International Filing Date: 28 July 2000 (28.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
S990659 30 July 1999 (30.07.1999) IE

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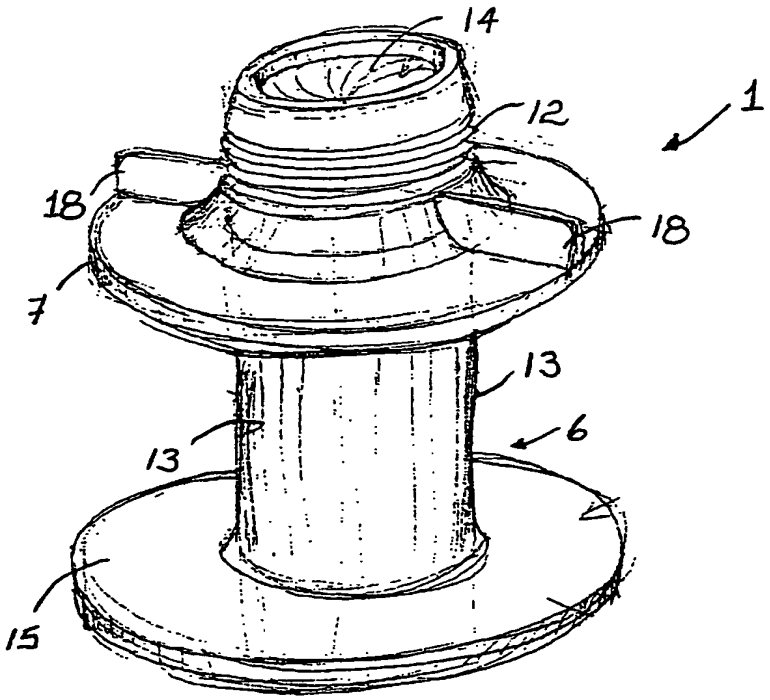
(81) Designated States *(national)*: CA, JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A SURGICAL DEVICE



(57) Abstract: A surgical device (1) for use in minimally invasive surgery is inserted into a body cavity. A trocar (5) is moved into a piercing position with a cutting tip (8) in contact with an inner wall (3) before the cutting tip (8) is pressed through the abdominal wall (2). When in position, the trocar (5) is unscrewed from a cannula (6) and the device (1) is secured with an anchor ring (7). The device (1) which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar (5) is directed away from the patient's organs during insertion.

WO 01/08563 A2

A SURGICAL DEVICE

The present invention relates to a surgical device and more particularly to a trocar and cannula for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and having sealed the incision with an access port. The access port enables hand assisted laproscopic surgery (HALS) or instrument assisted surgery to be performed. When the surgery requires the use of a second set of instruments, a trocar is often used to introduce a cannula as an alternative to a second incision and access port. A trocar is a surgical device designed to provide a small conduit known as a cannula through tissue to allow instruments such as an endoscope to be inserted into the body cavity.

The uses of trocar and cannula devices have a number of problems generally. Previously known cannulas are prone to allowing gas to escape from the body cavity when in position. The gas may escape through the cannula while a surgical instrument is in use or from around the incision. The provision of a suitable seal is essential in maintaining the correct pressure of gas within the body cavity, however, it is also essential to ensure that the seal is provided in a manner which does not limit a surgeon's mobility or cause unnecessary trauma. This can prove particularly problematic where the device is to be inserted in a narrow portion of the body cavity. Existing cannulas are also prone to being ejected from the body cavity due to gas pressure or instrument removal force, which is obviously unacceptable.

Additionally, fixing the cannula, once successfully in position, has presented difficulties. If the fixing arrangement is too large it can limit a surgeon's mobility and if the arrangement extends too far into the cavity there is a risk of unnecessary trauma. Furthermore, the insertion of the trocar often inadvertently causes unacceptable damage to a patient's tissue and internal organs.

It is an object of this invention to provide a method and apparatus for inserting and using a cannula, which will overcome the aforementioned problems.

It is a further object of the invention to provide a method and apparatus for securing and using a cannula, which will overcome the aforementioned problems and which will reduce the risk of secondary seeding of cancerous cells at port sites.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

wherein the trocar is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site. In this way accidental damage to the patient's tissue or organs is prevented as the cutting or piercing point of the trocar is directed away from the patient's body during the fixing procedure.

Ideally, the device is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site. Thus, the action of the cannula piercing the body cavity wall automatically draws the cannula into position.

Preferably, the trocar is removably mounted on the cannula.

In a particularly preferred embodiment, the trocar and cannula are connected with complementary engageable short threads on the trocar and cannula, such as quarter turn threads.

In one arrangement, the trocar is formed to provide a gas-tight cap for the cannula when mounted thereon. In this way as the trocar pierces outwardly from the body cavity there is no escape of gas, which would collapse the cavity. This is particularly useful when a single external valve is used.

In one arrangement, the trocar is provided with an integral cutting element. This facilitates the cutting of the body cavity wall to allow introduction of the cannula.

Preferably, the trocar incorporates an extension shoulder, thereby allowing the trocar to define a narrow incision, which is gently extended to ensure that the drawn cannula is firmly lodged in the body cavity wall preventing loss of gas from the cavity.

Preferably, the trocar incorporates guard means for protecting a surgeon's hand from being cut when being introduced into the body cavity or as the device cuts the patients skin thereby preventing injury to the surgeon.

Preferably, the cannula incorporates means for attaching the cannula to an interior of the body cavity when in position.

Ideally, the means for attaching the cannula to an interior of the body cavity is provided by an internal distal ring.

In one arrangement, the internal distal ring and the cannula are integrally formed as a single unit.

Preferably, the cannula incorporates one or more valves, internally or externally of the body cavity, to prevent loss of gas from the body cavity when the cannula is in position.

In one arrangement, the fixing means incorporates an anchor ring formed for releasable engagement with a proximal end of the cannula extending from the body when the cannula is in position in the body cavity. In this way, when the trocar has pierced the body cavity wall from within the cavity the portion of the cannula extending through the wall can be used to secure the cannula in position. This prevents tearing of the body tissue as the cannula is firmly attached to both internal and external walls of the body cavity.

Preferably, the anchor ring incorporates a thread for engaging on the same thread used to secure the trocar prior to installation of the cannula. This reduces the complexity of components and allows the threaded portion on the cannula to serve both functions.

In an alternative arrangement to that described above the valve is incorporated into the anchor ring.

In a particularly preferred embodiment of the invention the device incorporates an external seal and an internal valve, the seal and valve being mounted about opposing ends of the cannula.

Preferably, the cannula is integrally formed with the seal and valve.

In one arrangement, the valve is integrally formed at one end of the cannula and has means for releaseably engaging a seal housing at an opposing end.

Preferably, the seal housing incorporates a diaphragm seal.

In one arrangement, the seal housing defines an extended entry port.

Preferably, the entry port has a conical section.

In a preferred embodiment, the cannula incorporates an insufflation port. In this way the device may also incorporate the functionality required to inflate the body cavity in a single device. This ensures that the operating site is adequately and controllably inflated and that the component count is reduced, thereby, simplifying postoperative procedures.

Ideally, the insufflation port communicates with an insufflation lumen having insufflation ducts communicating between the port and the body cavity.

Preferably, the insufflation lumen is carried on an exterior surface of the cannula.

Preferably, the anchor ring incorporates finger grip means to facilitate engagement with the cannula.

Preferably, the anchor ring and or the distal ring incorporate cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

In a particularly preferred arrangement, the device incorporates a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

According to one aspect of the invention the device incorporates an adjustable pressure release valve. Thus, the surgeon may inflate the body cavity to a desired level and tenting or venting of additional gas added during surgery prevents tearing of tissue surrounding the incisions made. The surgeon is thereby assured of constant body cavity inflation.

According to another aspect of the invention there is provided a method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the trocar out to an operating site and inserting a cannula in the incision made using the trocar.

According to another aspect of the invention, there is provided a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery, the fixing means in turn comprising an inner seal and or an outer seal, the or each seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

In one embodiment the fixing means is provided by:-

an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

an external seal having an downwardly extending conduit carried on an external mounting ring,

the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

Preferably, the conduits are formed for slidable interengagement.

Ideally, the conduits incorporate a ratchet retainer. This allows one conduit to be slid into position with one conduit being accommodated within the other and the ratchet ensures that the device can accommodate a wide variety of tissue wall widths while also guaranteeing a suitable seal.

In one arrangement, the or each conduit is deformable to facilitate removal by disengaging the ratchet retainer.

Ideally, the, or each mounting ring has an associated pressure absorption and seal enhancement means, provided for example by a sponge.

In a particularly preferred embodiment, the cannula, when in position also incorporates a valve.

According to another aspect of the invention, the mounting rings are pivotally movable about the longitudinal axis. In this way the cannula may be positioned at an angle. This can allow a surgeon to position the cannula in such a way as to direct an inserted piece of equipment to an operating site or to facilitate insertion in a portion of the body cavity where access is limited. Pivotal movement of the mounting rings ensures that seal integrity is maintained.

According to a still further aspect of the invention, the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.

In one arrangement the cannula is provided by a section of pleated tubing carried on the cannula.

According to one aspect of the invention, the external mounting ring defines an entry funnel having an oversize entry aperture for receiving and facilitating insertion of a piece of medical equipment.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, an embodiment of a surgical device in accordance with the invention, in which:-

Fig. 1 is a perspective view of portion of a surgical device in accordance with the invention;

Fig. 2 is a sectional view of the surgical device of Fig. 1 in position on a patient;

Fig.3 is a side view of the surgical device in accordance with the invention in a piercing position;

Fig. 4 is a side view of the device in a partially placed position;

Fig. 5 is a side view of the device in a pre-locking position;

Fig. 6 is a side view of the device shown in Figs. 3 to 5 in an in use position;

Figs. 7 and 8 illustrate operation of a valve for use with the invention;

Fig. 9 is a sectional view of an alternative embodiment of a surgical device in accordance with the invention in position on a patient;

Fig. 10 is a top view of portion of the device shown in Fig. 9 in the direction of the arrows X – X;

Fig. 11 is a sectional view of a further embodiment of a surgical device in accordance with the invention in position on a patient;

Fig. 12 is a top view of portion of the device shown in Fig. 11 in the direction of the arrows XII – XII;

Fig. 13 is a sectional view of a surgical device in accordance with the invention;

Fig. 14 is a sectional view of an alternative embodiment of a surgical device in accordance with the invention in position on a patient;

Fig.15 is an enlarged sectional view of portion of the surgical device of Fig. 14;

Fig. 16 is a sectional view of a further alternative embodiment of a surgical device in accordance with the invention in an insertion position;

Fig. 17 is a sectional view of the surgical device of Fig. 16 in an in use position;

Fig. 18 is a sectional view of a still further alternative embodiment of a surgical device in accordance with the invention in an insertion position;

Fig. 19 is a sectional view of the device of Fig. 18 in an in use position;

Fig. 20 is a sectional view of a still further alternative embodiment of a surgical device in accordance with the invention;

Fig. 21 is a sectional view of a seal forming part of the invention;

Fig. 22 is an exploded view of discs forming part of the seal illustrated in Fig. 21;

Fig. 23 is a sectional view of an alternative seal forming part of the invention; and

Fig. 24 is a perspective view of the seal illustrated in Fig. 23.

Referring to the drawings, and initially to Figs. 1 to 8 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity. The cavity is covered by in this case an abdominal wall 2 having an internal cavity

wall 3 and an external wall 4. The internal cavity wall 3 is accessible to a surgeon through an access port (not shown)

In more detail, the device 1 has a trocar 5, a cannula 6 and an anchor ring 7. The trocar 5 has a cutting tip 8, a shoulder portion 9 and an internal thread (not shown) for connecting the trocar 5 to the cannula 6.

The cannula 6 has a threaded portion 12 for connection to the internal thread of the trocar 5 and for extending beyond the external wall 4 when in position. The cannula 6 also has a body section 13 housing a valve 14 to prevent escape of gas from the body cavity when in position and an integrally formed distal ring 15 for engaging the internal wall 3.

The anchor ring 7 has an internal threaded portion 17 formed for engagement with the cannula threaded portion 12 and finger grip means 18 for facilitating this engagement.

In use, and referring now in particular to Figs. 3 to 6 the device 1 is inserted into the body cavity. The trocar 5 is moved into a piercing position as shown in Fig.3 with cutting tip 8 in contact with the inner wall 3. The cutting tip 8 is then pressed through the abdominal wall 2 until the tip 8 and shoulder portion 9 extends beyond the external wall 4. When the distal ring 15 comes into contact with the internal wall 3 and the body section 13 is in the abdominal wall 2 the trocar 5 is unscrewed from the threaded portion 12 of the cannula 6. (See Fig. 4.)

The anchor ring 7 is then ready for engagement as shown in Fig. 5. The finger grip means 18 are used to engage the threaded portion 17 with the threaded portion 12 of the cannula 6 until the anchor ring 7 is firmly pressed against the external wall 4. (See Figs. 2 and 6)

The invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is directed away from the patient's body during insertion. This is achieved in a way that ensures that the cannula is automatically drawn into position.

It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.

It will also be understood that the method and apparatus described may with minor modifications and without departing from the scope of the invention, be used to insert the device from an exterior surface through the abdominal wall into a patient's interior.

To avoid unnecessarily obscuring the present invention, detailed description of the valve has not been included, as it will be apparent to those skilled in the art that a wide variety of valves may be successfully employed. One such possibility is a twist valve, but any suitable valve may be used.

Referring now to Figs. 7 and 8 there is illustrated one example of a valve for use with the device indicated generally by the reference numeral 700 in which parts illustrated in Figs. 1 to 6 are indicated by the same numerals generally. With the device in position the valve 700 is located within the body cavity. A pair of doors 701 hingedly connected to the cannula 6 provides the valve. The doors 701 are biased into a closed position by a rubber cover 702. When a surgical implement 703 is inserted into the cannula (See Fig. 8) the doors 701 are forced outwardly against the cover 702. The cover 702 seals around the surgical implement 703 preventing escape of air from the cavity and as the implement is removed they also act to close the doors 701.

Referring now to Figs. 9 and 10 there is illustrated a further embodiment of a surgical device indicated generally by the reference numeral 900 in which parts similar to those described with reference to Figs. 1 to 8 are identified by the same numerals generally.

In this embodiment, the device 900 incorporates a releaseably attachable external seal housing 901 and an internal one way valve 902 mounted about opposing ends of the cannula 6. The housing 901 is located on the cannula 6 when in position on the patient using O rings 905. The housing 901 incorporates a diaphragm seal 903 and defines an outwardly directed extended entry port indicated at 904. The entry port 904 has a conical

section and is so formed to facilitate insertion of a surgical device by directing the device to the cannula 6. The housing 901 also defines an insufflation port 910 for receiving insufflation gases. These gasses are routed to the body cavity to ensure adequate and controlled inflation through insufflation ducts 911 carried in an insufflation lumen 912. The lumen 912 is carried on an exterior surface of the cannula 6 and terminates at the one way valve 903 with an insufflation outlet 913.

In use, the device 900 is positioned on the patient substantially as described with reference to Figs. 1 to 8. When the cannula 6 is in position the housing 901 is fixed in position using the O rings 905. The body cavity may then be inflated. A gas source (not shown) is connected with a pipe to the insufflation port 910. The gas is routed to the body cavity through the insufflation ducts 911 of the insufflation lumen 912 and out into the cavity through the insufflation outlet 913.

Once inflated instruments are passed through the diaphragm seal 903 to enter the cannula 6 having first been introduced and guided into position by a tapering internal surface of the entry port 904. Instruments are then passed down the cannula 6 and into the inflated body cavity through the one way valve 902.

It will be understood that a cannula sheath separated from the cannula body and running along the cannula exterior may equally provide the insufflation lumen.

Referring now to Figs. 11 and 12 there is illustrated a further embodiment of a surgical device indicated generally by the reference numeral 1100 in which parts similar to those described with reference to Figs. 1 to 10 are identified by the same numerals generally.

In this embodiment, the cannula 6 terminates in the body cavity with a one way valve 1101. Compressing a thin sleeve 1102 between two semi-circular, flexible foam pieces 1103 forms the valve 1101. The valve allows for the insertion of surgical implements and prevents the escape of gas from the body cavity.

It will be noted that while threaded engagement of the component parts of the device is described throughout any suitable method of engagement is acceptable.

It will also be noted that the distal ring and anchor ring may be suitably coated with airtight, antiseptic and or shock absorbent material to prevent trauma to the abdominal wall and loss of gas from the body cavity.

It will be understood that the anchor ring may be extended to incorporate a valve, which allows insertion of instruments thereby reducing the weight of the device.

It will also be understood that the device may incorporate a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

It will further be understood that the device may incorporate an adjustable pressure release valve. This will allow the surgeon to inflate the body cavity to a desired level and ensure a constant level of body cavity inflation by continuously supplying inflation gas and venting any excess through the pressure release valve. This prevents excessive movement of the cavity wall during the procedure, which can inconvenience the surgeon and cause trauma to the patient

Referring to the drawings again and now to Fig. 13 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1300. The surgical device 1300 is formed for use in minimally invasive surgery of the type using an inflated body cavity. The cavity is covered by in this case an abdominal wall 1302 having an internal cavity wall 1303 and an external wall 1304. The internal cavity wall 1303 is accessible to a surgeon through an access port (not shown)

In more detail, the device 1300 has a fixing means provided by an inner sealing ring 1330 and an outer sealing ring 1340. The outer ring 1340 is movable along a longitudinal axis of a cannula 1320 to secure the device 1300 in position on the abdominal wall 1302. The cannula 1320 is defined by the interengagement of an upwardly extending conduit 1331

carried on the ring 1330 and a downwardly extending conduit 1341 carried on the ring 1340. The conduit 1341 has a ratcheted retainer exterior surface portion (not shown) and is dimensioned to slidably engage and ratchet within the conduit 1331 against a ratcheted interior portion thereof (not shown). Once engaged the conduits 1331 and 1341 define the cannula 1320. This form of engagement allows the device 1300 to accommodate a wide variety of walls 1302 while also guaranteeing a suitable seal. The outer ring 1340 has an absorbent sealing sponge 1342. The inner sealing ring 1330 also has a sponge 1332 and a valve 1343 to prevent escape of gas from the cavity.

In use, the device 1300 is inserted into the body cavity by first introducing the inner sealing ring 1330 into the cavity and pushing the conduit 1331 through the wall 1302. Pushing continues until the sponge 1332 comes into contact with the internal cavity wall 1303. The ring 1340 is then positioned over the conduit 1331 with the conduit 1341 extending downwards. The conduit 1341 is then introduced into the conduit 1331 and slideably engaged. Sliding continues until the sponge 1342 presses snugly against the external wall 1304. The device is securely held as the ratcheted portions of the conduits ensure positive contact. The valve 1343 prevents gas from escaping during an operation.

Referring now to Figs. 14 and 17 there is shown an alternative device indicated generally by the reference numeral 2000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. The device 2000 in use operates in a similar fashion but in this embodiment a conduit 1410 is greatly shortened over the conduit 1331 of Fig. 13. A conduit 1310 in this instance has a ratcheted surface 1330 along an exterior portion. A ratchet retainer is provided by the slidable engagement of the surface 1330 against a grip 2010 carried on the ring 1340.

Release of the device 2000 is effected in this instance by squeezing the grip 2010 toward the conduit 1310 to disengage the grip 2010 from the surface 1330.

Referring now to Figs. 16 and 17 there is shown a further embodiment of a device indicated generally by the reference numeral 4000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. The device 4000 has an internal ring

4300 and an external ring 4400 pivotally mounted on a cannula 4200. Engagement of the device 4000 and the rings 4300 and 4400 is similar to that described above. In this embodiment the pivotal movement of the rings about the longitudinal axis of the cannula 4200 allows the cannula to be inserted at an angle. As the ring 4300 approaches the internal wall 1330 the pivotal movement allows the ring 4300 to move to contour the internal wall 1303. Similarly the external ring 4400 moulds the external wall 1304. This movement allows a surgeon to position the cannula in such a way as to direct an inserted piece of equipment to an operating site or to facilitate insertion in a portion of the body cavity where access is limited. Pivotal movement of the mounting rings also ensures that seal integrity is maintained.

Referring now to Figs. 18 and 19 there is shown a further embodiment of a device indicated generally by the reference numeral 5000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. In this embodiment, the cannula 1320 incorporates a pleated tubing 5500. As the ring 1340 is positioned, the trocar 1350 is removed and the cannula 5500 is collapsed. This collapse causes the cannula 5500 to expand and provides an additional seal around the body incision.

Now referring to Fig. 20 there is shown a further embodiment of a device indicated generally by the reference numeral 8000. In this embodiment the ring 8400 defines a funnel entry 8450 to facilitate insertion of medical instruments. This embodiment also has a foam spacer 8460 which is particular useful when it is desired to extend the cannula.

It is envisaged that the cannula may incorporate a deformable web, such as corrugated tubing, which will deform when in position on a patient to stabilise the cannula and to provide a seal.

It will be understood that the device may include a number of seals and that these seals may operate independently or in combination. For example, the device may include a seal adjacent the outer ring which will engage only when an instrument has been passed into the body cavity and there is a risk of gas escaping from a seal adjacent the inner sealing ring.

Referring now to Figs. 21 and 22, there is illustrated one such seal forming part of the invention indicated generally by the reference numeral 9000. The seal 9000 has a locking ring 9010, a diaphragm seal 9020 and two slit seals 9030, 9040. The slit seals 9030, 9040 each have four orthogonally arranged slits 9050 radiating from the center and the seals 9030, 9040 are offset by forty five degrees. In use, a seal is provided as an instrument is introduced by the action of pressing the instrument against the slits 9050. When the device is removed, the slits 9050 return to normal resting position offset by forty five degrees from the slit above thereby maintaining an overall seal.

Figs. 23 and 24 show a similar seal to that illustrated in Figs. 21 and 22 illustrated generally by the reference numeral 9500. In this seal 9500 the slits 9050 are orthogonally directed as before on a concave disc 9510. The concave nature of the disc 9510 ensures that the slits 9050 are pressed together. Upward movement beyond a resting position of any portion of the disc 9510 is prevented by the provision of four webs 9511 on the underside of the disc 9510 intermediate the slits 9050.

It will be noted that the invention is directed to wards providing a reduced trauma, low profile, airtight cannula. It will be appreciated also that the device is particularly suited for use with a trocar and is ideal for applications in which the device is positioned from within the body cavity. Thus, the invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is directed away from the patient's body during insertion.

It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.

It will also be understood that the method and apparatus described may with minor modifications and without departing from the scope of the invention, be used to insert the device from an exterior surface through the abdominal wall into a patient's interior.

To avoid unnecessarily obscuring the present invention, detailed description of the valve has not been included, as it will be apparent to those skilled in the art that a wide variety of valves may be successfully employed. One such possibility is a twist valve, but any suitable valve may be used.

It will be noted that the external ring may define a circular entry port or a partial funnel with an oversized opening to facilitate threading of components into the cannula.

It will also be noted that the internal and external rings may be suitably coated with airtight, antiseptic and or shock absorbent material to prevent trauma to the abdominal wall and loss of gas from the body cavity.

It will be understood that the anchor ring may be extended to incorporate a valve, which allows insertion of instruments thereby reducing the weight of the device.

It will also be understood that the device may incorporate a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

It will further be understood that the device may incorporate an adjustable pressure release valve. This will allow the surgeon to inflate the body cavity to a desired level and ensure a constant level of body cavity inflation by continuously supplying inflation gas and venting any excess through the pressure release valve. This prevents excessive movement of the cavity wall during the procedure, which can inconvenience the surgeon and cause trauma to the patient

It will be noted that the devices described herein may be provided as modular devices and that the device may be formed to accommodate different sizes of seals and valves to allow the device a broad scope of application.

It will also be noted that the device may optionally include an insufflation lumen or conduit to provide pneumoperitoneum at the operating site.

It will also be understood that the component parts of the device may be transparent to facilitate a surgeon during the course of an operation.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention as defined in the appended claims.

CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula (6) defining a conduit into the body cavity;

a trocar (5) carried on the cannula (6) and formed for piercing or cutting tissue to position the cannula (6); and

fixing means for removably securing the cannula (6) in position on the patient during surgery,

characterised in that the trocar (5) is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site.

2. A surgical device as claimed in claim 1, wherein the trocar (5) is removably mounted on the cannula (6).

3. A surgical device as claimed in claim 2, wherein the trocar and cannula are removably mounted with complementary engageable short threads.

4. A surgical device as claimed in claim 2 or 3, in which the trocar is formed for gas-tight mounting on the cannula.

5. A surgical device as claimed in any preceding claim, wherein the trocar is provided with an integral cutting element, thereby facilitating the cutting of the body cavity wall to allow introduction of the cannula.

6. A surgical device as claimed in claim 5, wherein the trocar incorporates an extension shoulder.

7. A surgical device as claimed in any preceding claim, wherein the trocar incorporates guard means for preventing injury to the surgeon.

8. A surgical device as claimed in any preceding claim, wherein the cannula incorporates means for releaseably attaching the cannula to an interior of the body cavity.

9. A surgical device as claimed in claim 8, wherein the means for attaching the cannula to an interior of the body cavity is provided by an internal distal ring.

10. A surgical device as claimed in claim 10, in which the internal distal ring and the cannula are integrally formed as a single unit.

11. A surgical device as claimed in any preceding claim, wherein the cannula incorporates a valve to prevent loss of gas from the body cavity when the cannula is in position.

12. A surgical device as claimed in any preceding claim, wherein the fixing means incorporates an anchor ring formed for releasable engagement with a proximal end of the cannula extending from the body when the cannula is in position in the body cavity.

13. A surgical device as claimed in claim 12, wherein the anchor ring incorporates a thread for engaging on the same thread used to secure the trocar prior to installation of the cannula.

14. A surgical device as claimed in claim 12 or 13, wherein the anchor ring incorporates a valve.

15. A surgical device as claimed in any preceding claim, incorporating an external seal and an internal valve, the seal and valve being mounted about opposing ends of the cannula.

16. A surgical device as claimed in claim 15, wherein the cannula is integrally formed with the seal and valve.

17. A surgical device as claimed in claim 15 or 16, wherein the valve is integrally formed at one end of the cannula and has means for releaseably engaging a seal housing at an opposing end.

18. A surgical device as claimed in claim 17, in which the seal housing incorporates a diaphragm seal.

19. A surgical device as claimed in any of claims 15 to 18, wherein the seal housing defines an extended entry port.

20. A surgical device as claimed in claim 19, wherein the entry port has a conical section.

21. A surgical device as claimed in any preceding claim, wherein the cannula incorporates an insufflation port.

22. A surgical device as claimed in claim 21, in which the insufflation port communicates with an insufflation lumen having insufflation ducts communicating between the port and the body cavity.

23. A surgical device as claimed in claim 22,wherein the insufflation lumen is carried on an exterior surface of the cannula.

24. A surgical device as claimed in any of claims 13 to 23, wherein the anchor ring incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

25. A surgical device as claimed in any of claims 13 to 24, wherein the distal ring incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

26. A surgical device as claimed in any preceding claim, incorporating a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to being fixed in position on a patient.

27. A surgical device as claimed in any preceding claim, incorporating an adjustable pressure release valve.

28. A method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the trocar out to an operating site and inserting a cannula in the incision made using the trocar.

29. A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing

means for removably securing the cannula in position on the patient during surgery, the fixing means in turn having at least one seal, the or each seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

30. A surgical device as claimed in claim 29, in which the fixing means is provided by:- an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

an external seal having an downwardly extending conduit carried on an external mounting ring, the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

31. A surgical device as claimed in claim 30, wherein the conduits are formed for slidable interengagement.

32. A surgical device as claimed in claim 29 or 30, in which the conduits incorporate a ratchet retainer.

33. A surgical device as claimed in claim 32, wherein the or each conduit is deformable to facilitate removal by disengaging the ratchet retainer.

34. A surgical device as claimed in any of claims 30 to 33, wherein the, or each mounting ring has an associated pressure absorption and seal enhancement means.

35. A surgical device as claimed in any of claims 30 to 34, wherein the cannula incorporates a valve.

36. A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery

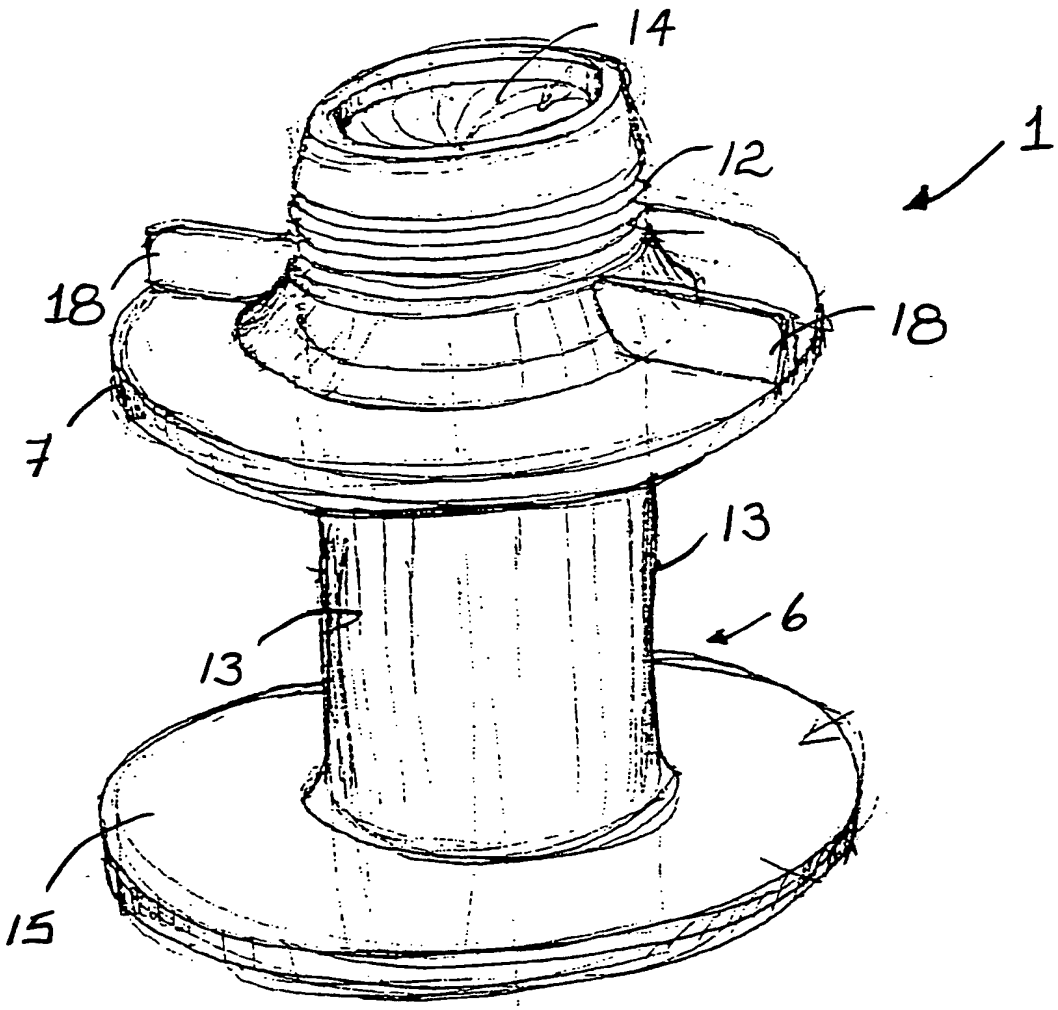
provided by an external and an internal mounting ring, one or both rings being pivotally movable about a longitudinal axis of the cannula.

37. A surgical device as claimed in claim 36, in which the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.

38. A surgical device as claimed in claim 37, in which the cannula is provided by a section of pleated tubing carried on the device.

39. A surgical device as claimed in claim 38, wherein the external mounting ring defines an entry funnel having an oversize entry aperture for receiving and facilitating insertion of a piece of medical equipment.

Fig. 1



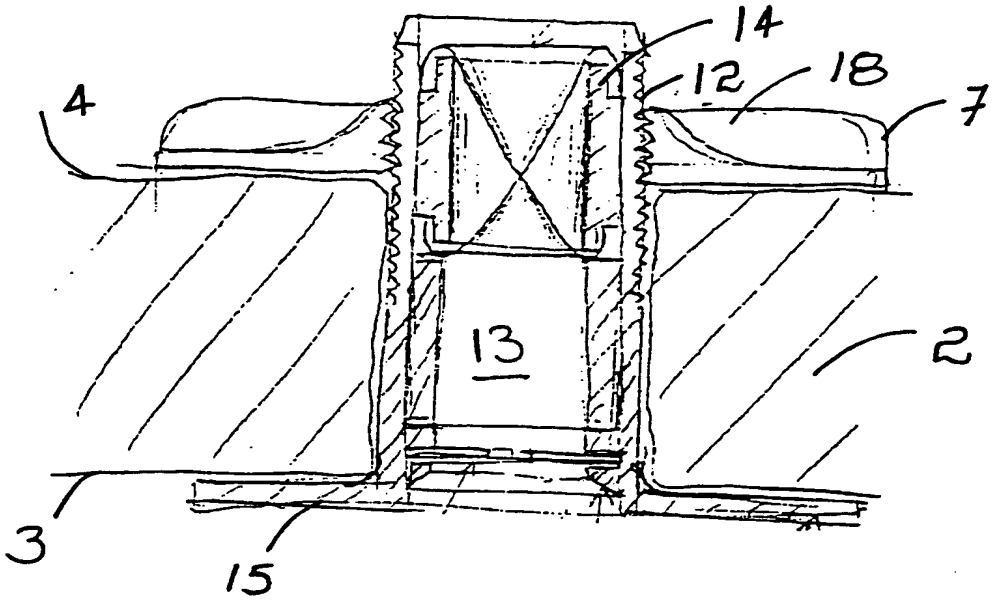


Fig. 2

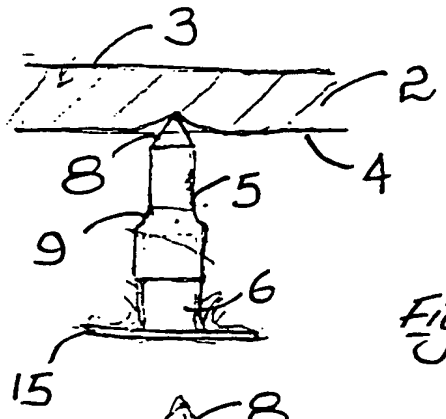


Fig. 3

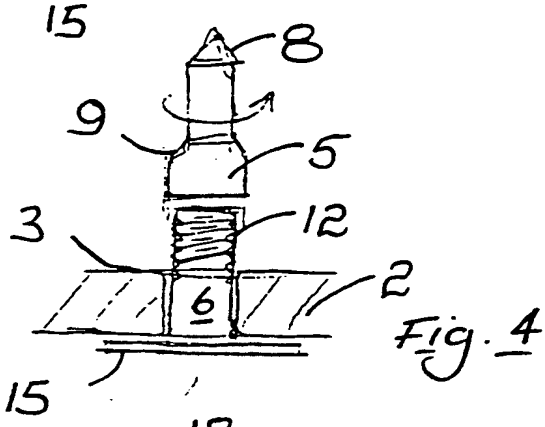


Fig. 4

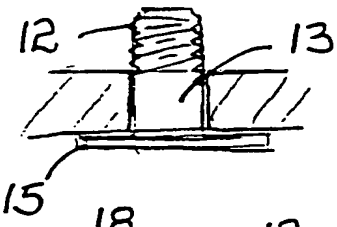


Fig. 5

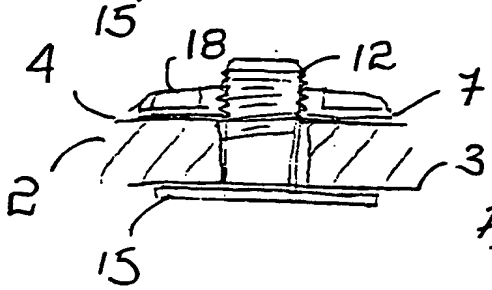
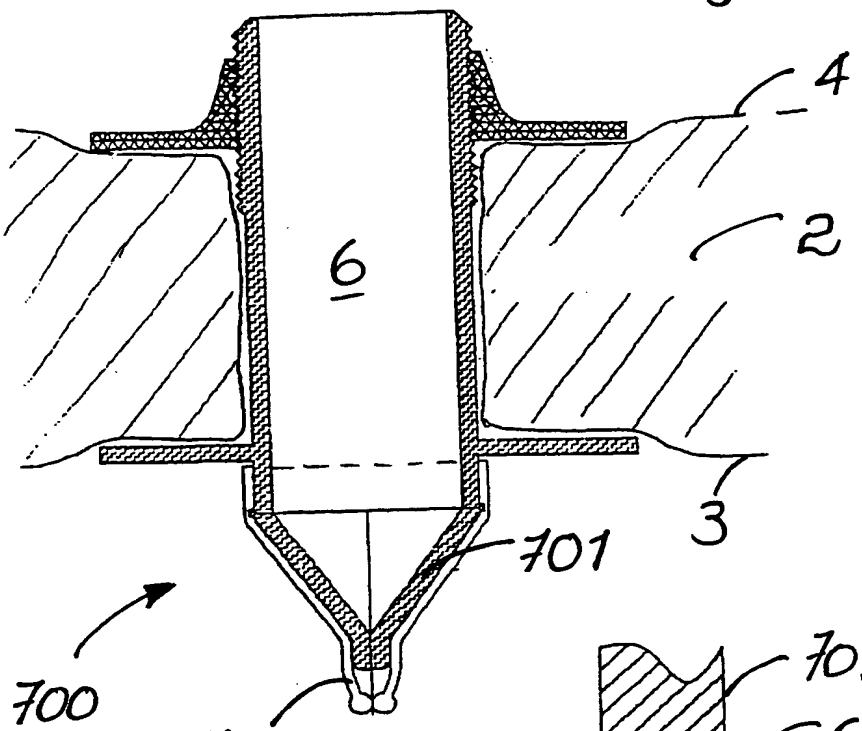


Fig. 6

Fig. 7



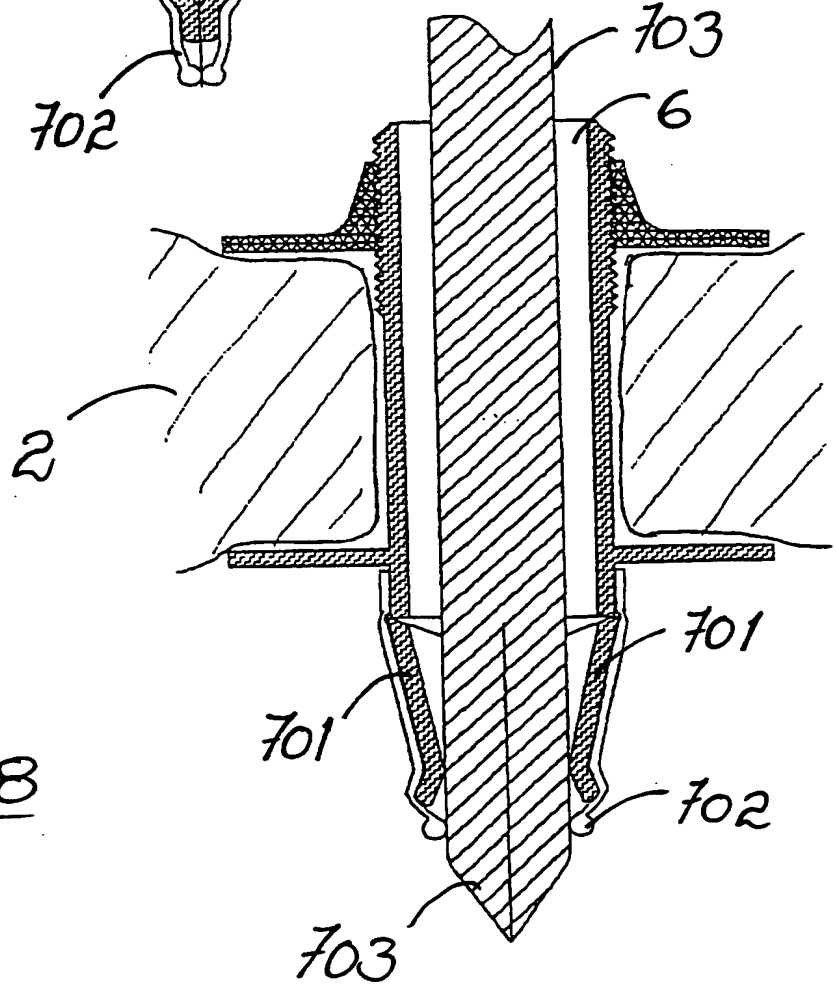


Fig. 8

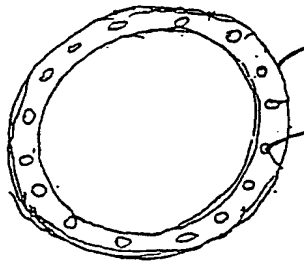


Fig. 10

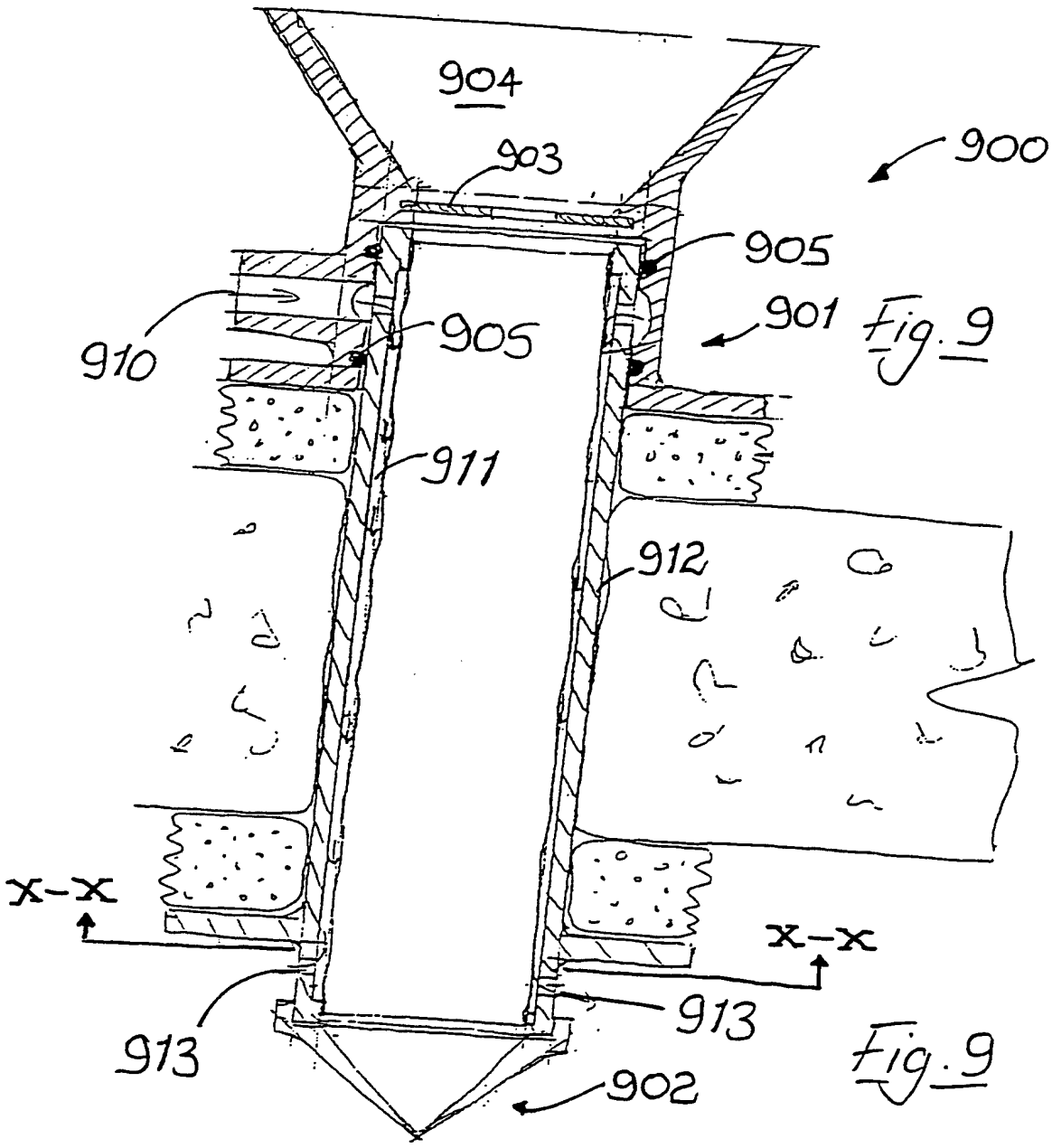


Fig. 9

Fig. 9

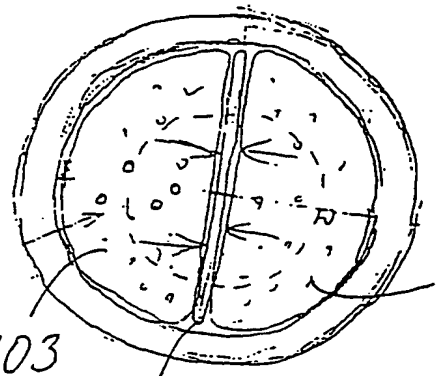


Fig. 12

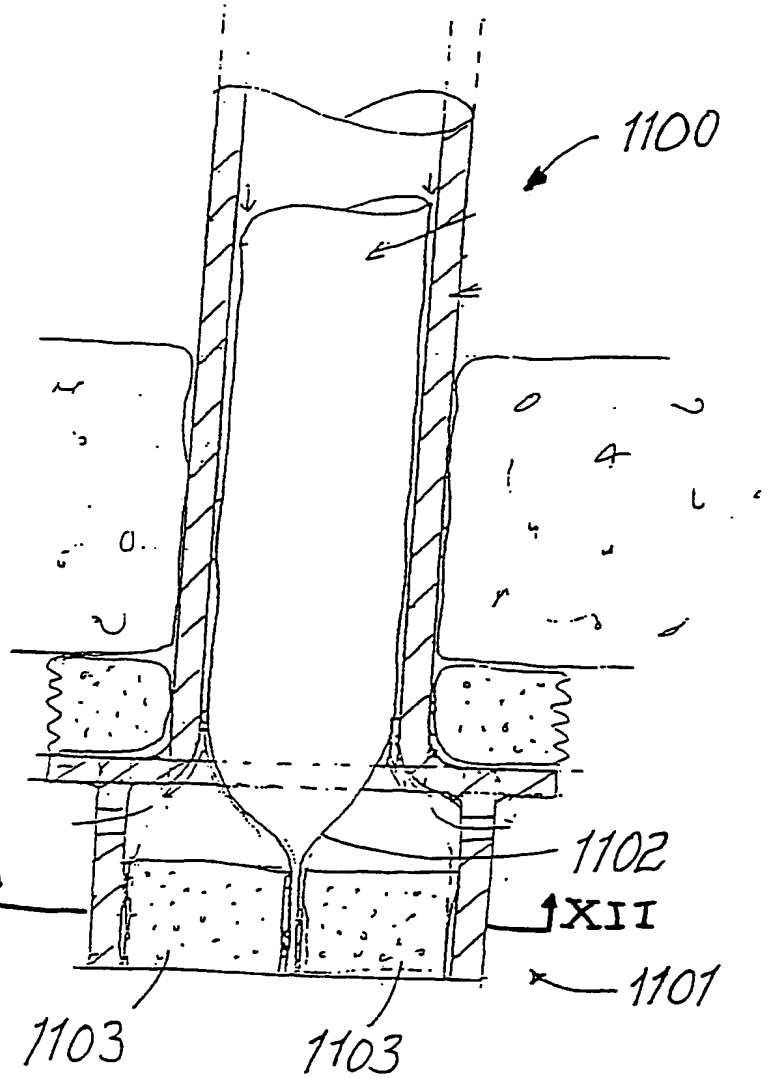


Fig. 11

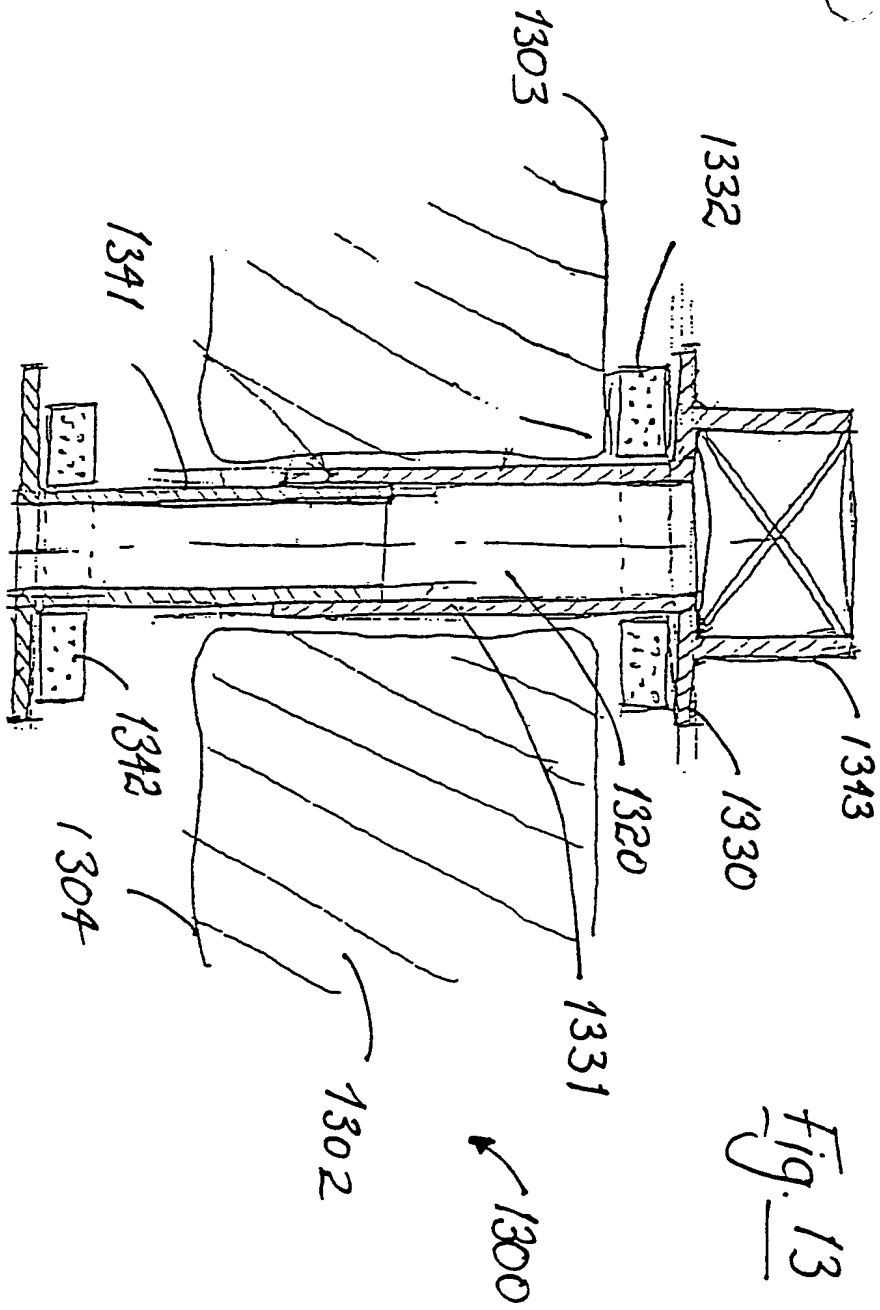


Fig. 13

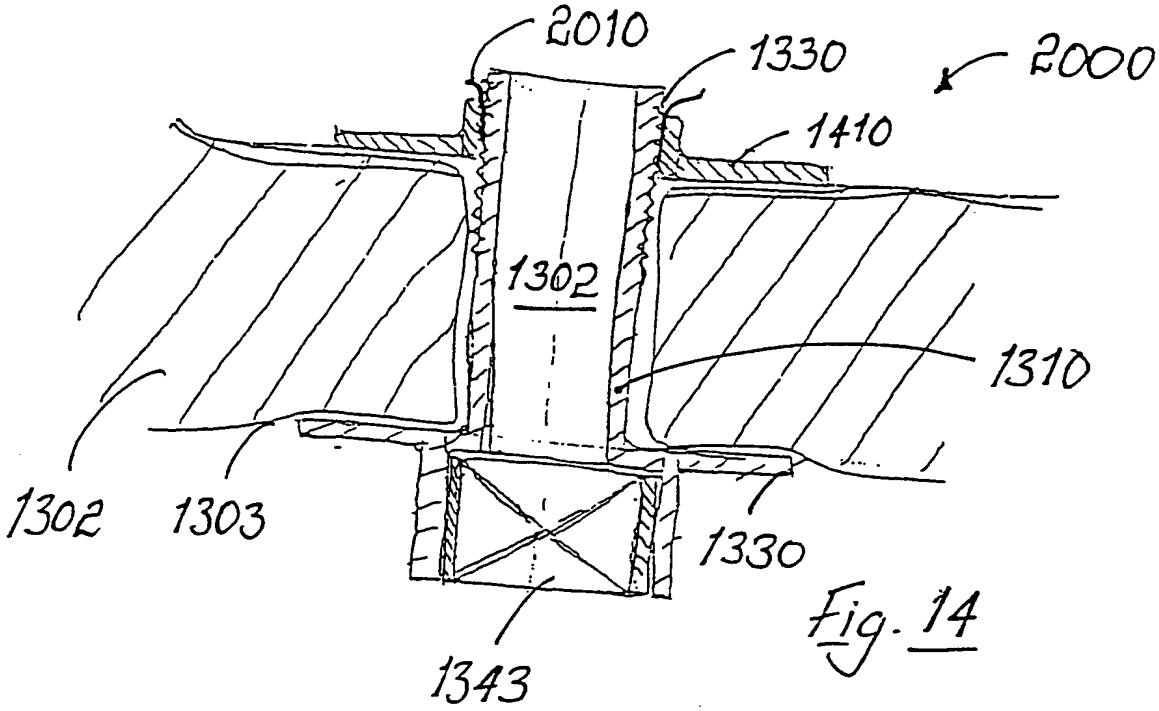

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Fig. 14

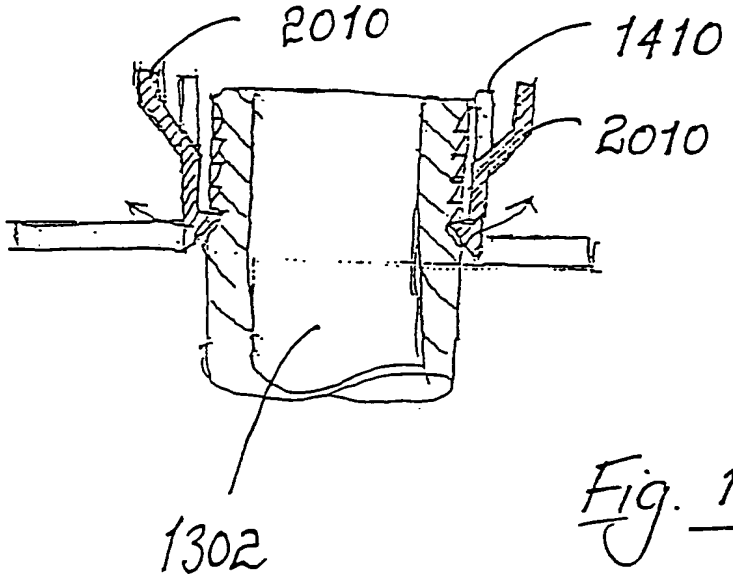
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Fig. 15

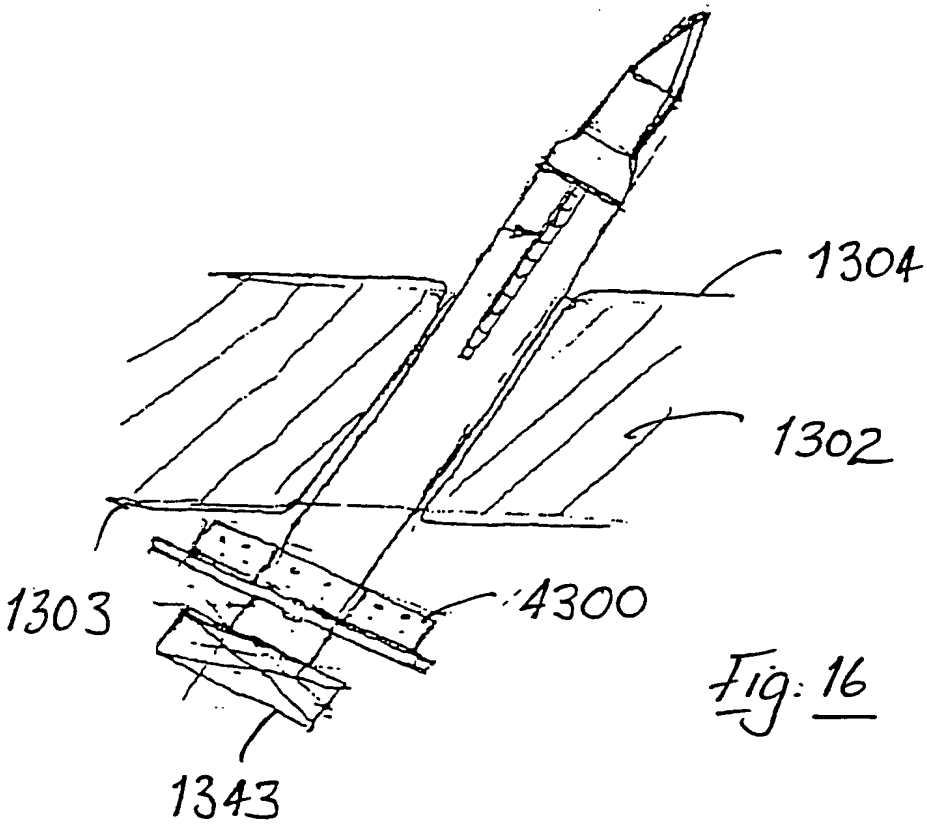


Fig. 16

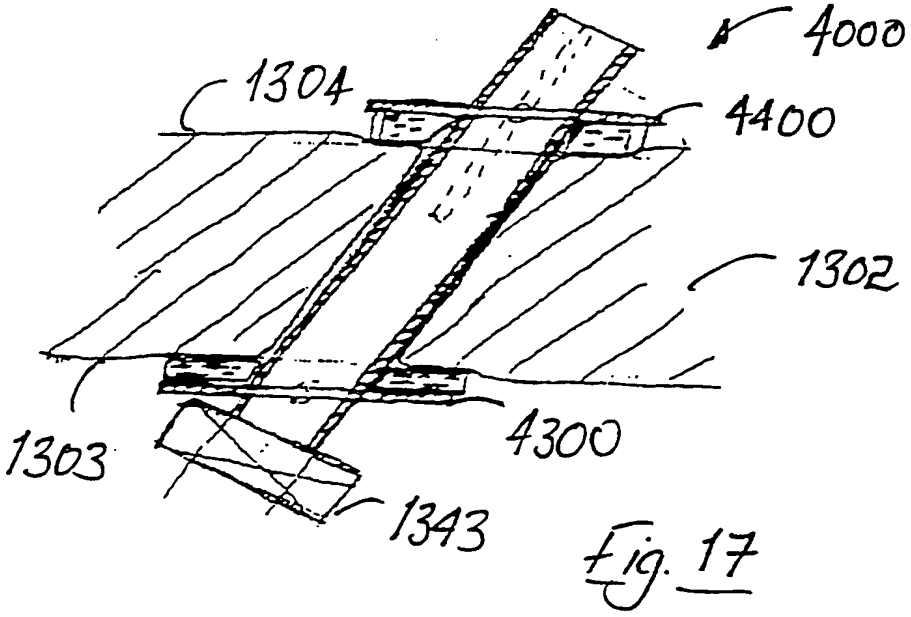


Fig. 17

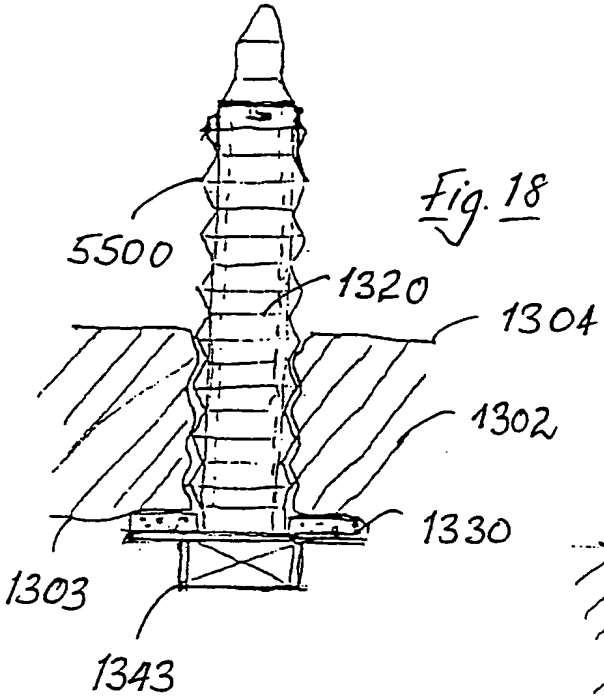


Fig. 18

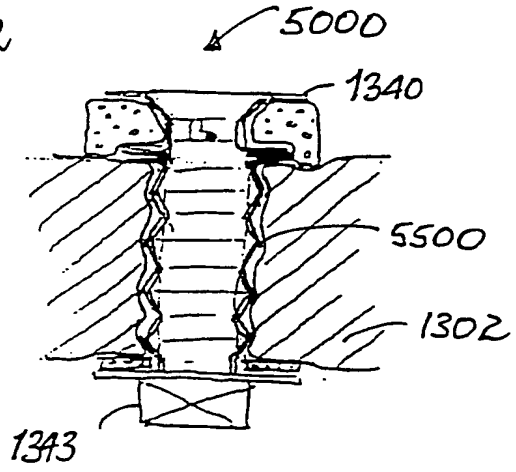


Fig. 19

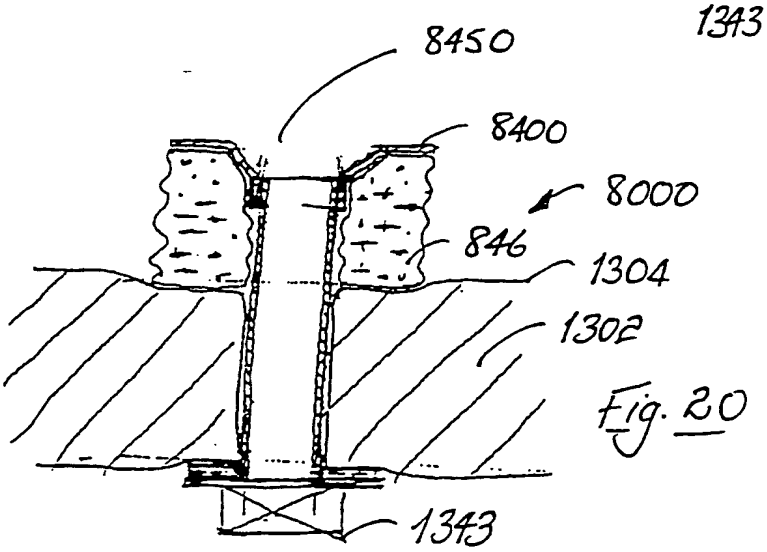


Fig. 20

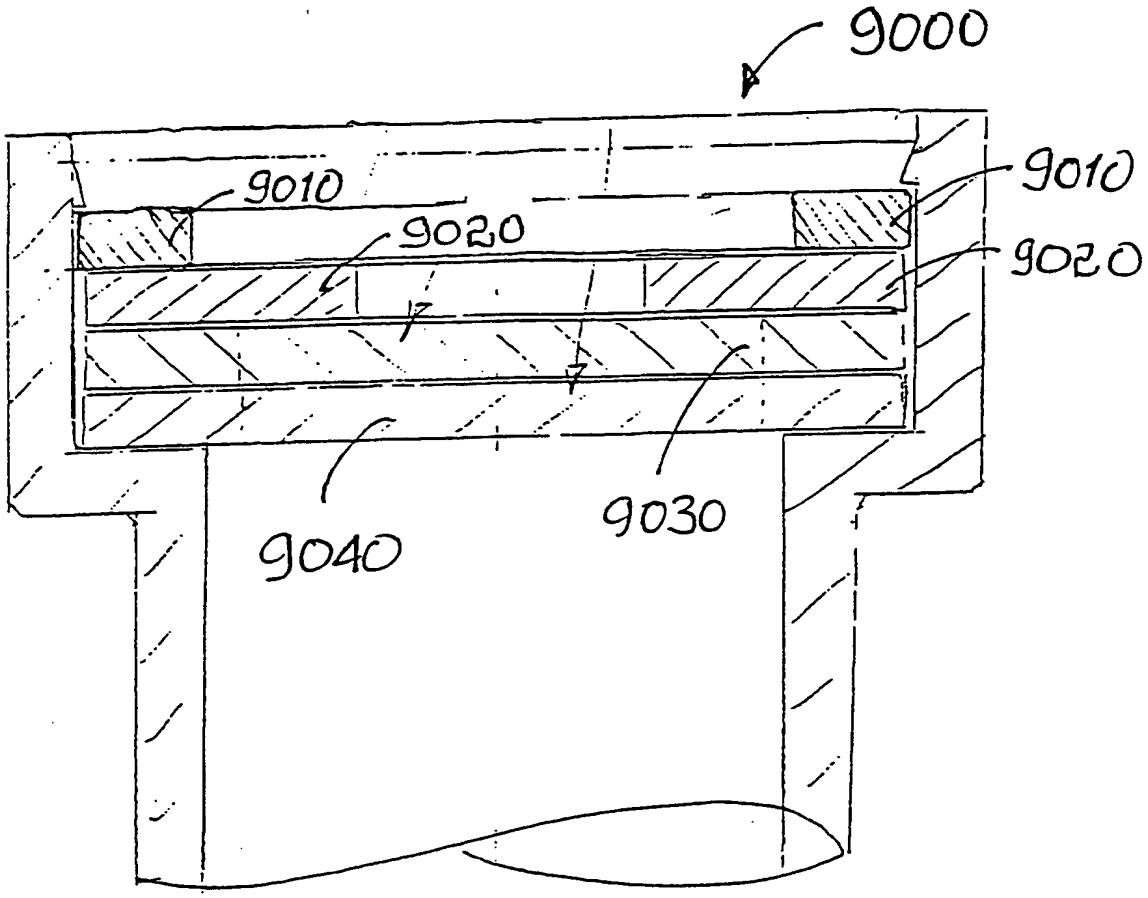


Fig. 21

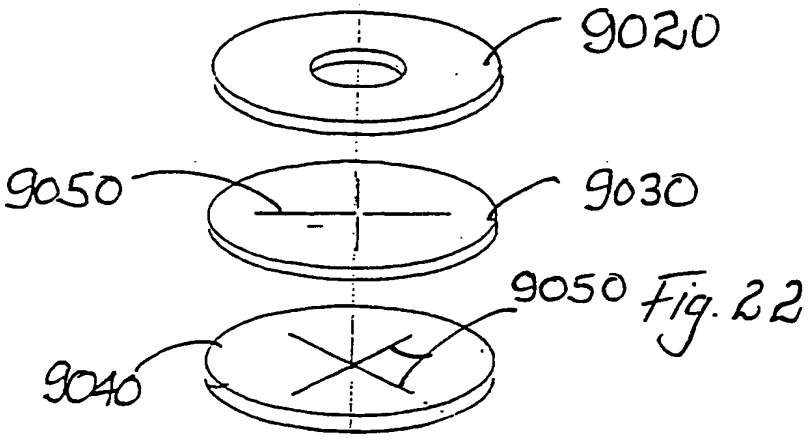
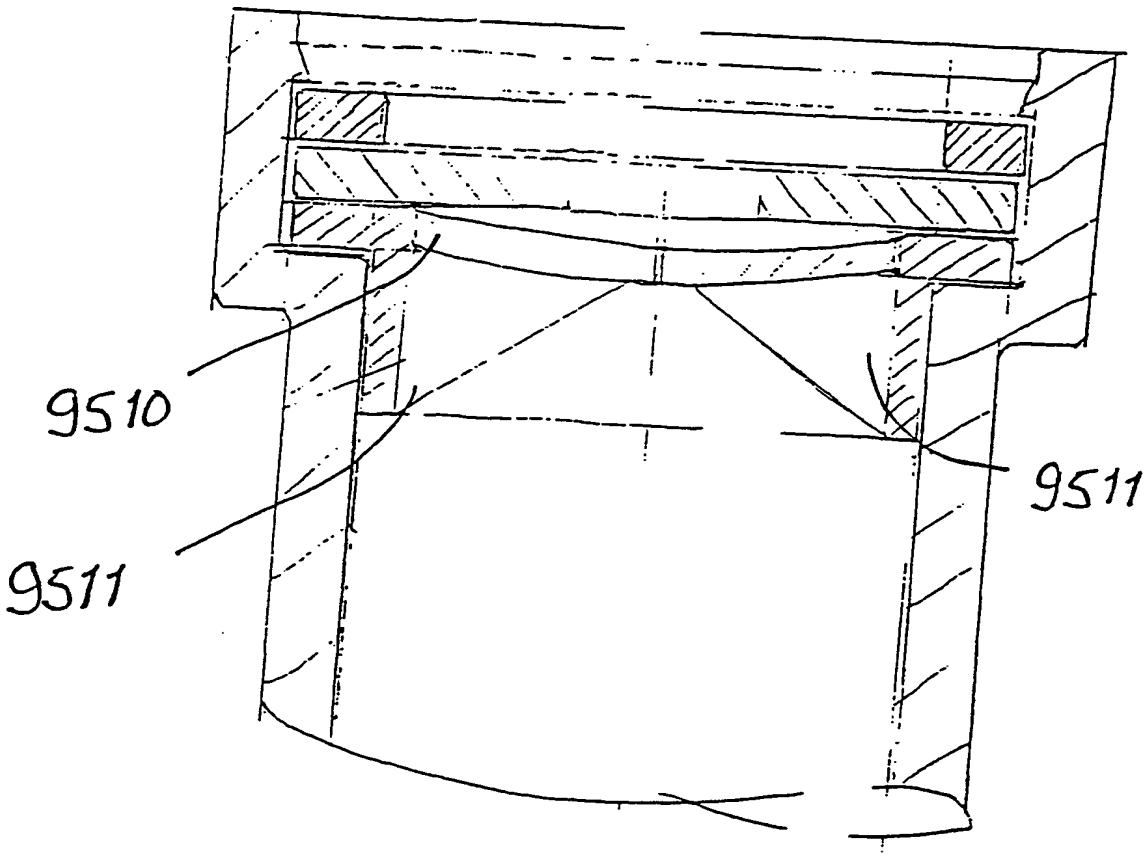


Fig. 22

9500

Fig. 23



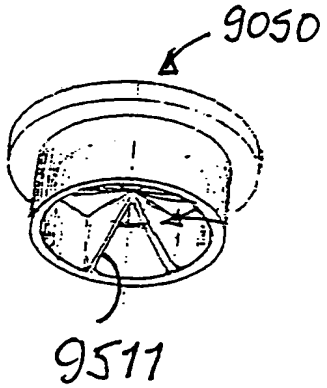


Fig. 24

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/08563 A3

(51) International Patent Classification[7]: A61B 17/34

(21) International Application Number: PCT/IE00/00093

(22) International Filing Date: 28 July 2000 (28.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
S990659 30 July 1999 (30.07.1999) IE

(71) Applicant *(for all designated States except US)*: **GAYA LIMITED** [IE/IE]; 2-3 Sandyford Village, Sandyford, Dublin 18 (IE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **CALDWELL, Martin** [IE/IE]; 37 Mount Pleasant Square, Ranelagh, Dublin 6 (IE). **CUMMINS, Christopher** [IE/IE]; 54 Knockowen Road, Tullamore, County Offaly (IE).

(74) Agent: **MACLACHLAN & DONALDSON**; 47 Merrion Square, Dublin 2 (IE).

(81) Designated States *(national)*: CA, JP, US.

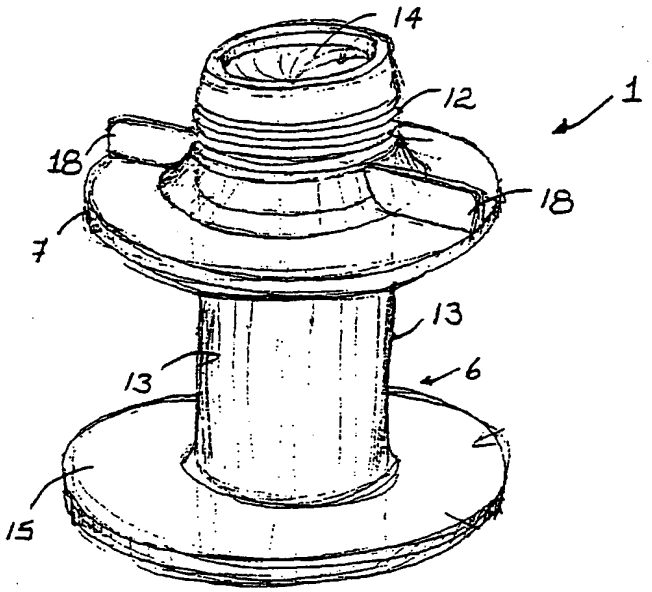
(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *with international search report*

(88) Date of publication of the international search report:
10 January 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A SURGICAL ACCESS DEVICE



(57) Abstract: A surgical device (1) for use in minimally invasive surgery is inserted into a body cavity. A trocar (5) is moved into a piercing position with a cutting tip (8) in contact with an inner wall (3) before the cutting tip (8) is pressed through the abdominal wall (2). When in position, the trocar (5) is unscrewed from a cannula (6) and the device (1) is secured with an anchor ring (7). The device (1) which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar (5) is directed away from the patient's organs during insertion.

WO 01/08563 A3

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
P8145.WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IE 00/ 00093	28/07/2000	30/07/1999
Applicant		
GAYA LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   A SURGICAL ACCESS DEVICE

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATI L SEARCH REPORT

International application No.
PCT/IE 00/00093

Box I Observations wh re certain claims were found unsearchabl (Continuation of it m 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-27

   Surgical device comprising a cannula, a trocar carried on said cannula and suitable to be inserted in the body and piercing tissue outwardly and fixing means for securing the cannula.

2. Claims: 29-35

   Surgical device comprising a cannula, fixing means for securing the cannula, the fixing means having at least one seal.

3. Claims: 36-39

   Surgical device comprising a cannula, fixing means for securing the cannula provided by an external and internal mounting ring one or both being pivotally movable

INTERNATIONAL SEARCH REPORT

International Application No
IE 00/00093

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 658 306 A (KIETURAKIS MACIEJ J ET AL) 19 August 1997 (1997-08-19) column 11, line 63 -column 12, line 50; figures 19,20	1,2,5, 11-14, 21-23 3,4,7-10
Y	WO 95 11050 A (RAMMLER) 27 April 1995 (1995-04-27) abstract; figures 6,9,10	3,4
Y	WO 96 10432 A (YOON INBAE) 11 April 1996 (1996-04-11) abstract; figure 1	7
Y	US 4 573 576 A (KROL) 4 March 1986 (1986-03-04) column 2, line 53 - line 58; figures 6,7	8-10

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 June 2001	20. 06. 01

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Moers, R

3

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/IE 00/00093

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 830 191 A (NAGAO REX ET AL) 3 November 1998 (1998-11-03)	8-10
Y	abstract; figures 17-22	30,31
X	column 9, line 43 - line 62; figures 33,34	36
A	EP 0 542 428 A (DEXIDE INC) 19 May 1993 (1993-05-19)	1
X	column 9, line 36 - line 49; figures 1,9	29
X	WO 97 31578 A (MOENNING STEPHEN P) 4 September 1997 (1997-09-04) abstract; figures 5,7	29-31
X	US 5 882 344 A (STOUDER JR ALBERT E) 16 March 1999 (1999-03-16)	29,32-35
Y	column 6, line 9 - line 57; figure 8	30,31
X	EP 0 487 175 A (CASTILLENTI THOMAS A) 27 May 1992 (1992-05-27) abstract; figures 5,6	29,32-35
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A	figure 20	39
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